BIMECTIN POUR-ON - ivermectin solution

Bimeda, Inc. Division of Cross Vetpharm Group

INDICATIONS

Bimectin (ivermectin) Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective treatment and control of these parasites.

Gastrointestinal Roundworms

Ostertagia ostertagi (adults and L₄)

(indcluding inhibited state)

 $\begin{array}{lll} \textit{Haemonchus placei} & (adults \ and \ L_4) \\ \textit{Trichostrongylus axei} & (adults \ and \ L_4) \\ \textit{Cooperia oncophora} & (adults \ and \ L_4) \\ \textit{Cooperia punctata} & (adults \ and \ L_4) \\ \textit{Cooperia surnabada} & (adults \ and \ L_4) \end{array}$

Strongyloides papillosus (adults)

Oesophagostomum radiatum (adults and L₄)

Lungworms

Dictyocaulus viviparus (adults and L₄)

Cattle Grubs

Hypoderma bovis

Mites

Sarcoptes scabei var. bovis

Lice

Lingonathus vituli

Haematopinus eurysternus

Damalia bovis

Solenopotes capillatus

Horn Flies

Haematobia irritans

Treatment of Cattle for Horn Flies: Bimectin (ivermectin) Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Bimectin (ivermectin) Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the must effective timing of applications.

Persistent Activity: Bimectin (ivermectin) Pour-On has been proved to effectively control infections and to protect cattle from reinfection with *Ostertagia Ostertagi, Oesophagostomum radiatum*, *Haemonchus placei, Trichostrongyles axei, Cooperia punctata* and *Cooperia oncophora* for 14 days after treatment.

DOSAGE

Dosage: The dose rate is 1 mL for each 22lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

Administration: Squeeze-Measure-Pour System (1 Liter Bottle with 25 mL Measuring Cap)

Attach metering cap to the bottle.

Select the correct dose rate by rotating the adjuster cap in either direction to position the dose indicator to the appropriate dose. Gently squeeze the bottle to fill to level (any excess will return to the bottle) and then tip and apply to animal along the topline. *BackPack* (84.5 fl oz/2.5 Liter Pack and 169 fl. oz/5 Liter Pack.

Connect the applicator gun to the backpack as follows: Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage).

Replace the shipping cap with the draw-off cap and tighten down.

Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks.

Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

Free standing 338 fl. oz./10 Liter bottle and 676 fl. oz./20 Liter bottle

Connect the applicator gun to the 338 fl. oz./10 L and 676 fl. oz./20 L bottle as follows: Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supply

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MODE OF ACTION

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channel, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety of compounds of this class is attributable to the fact that mammals do not have the glutamate-gated chloride channel, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channel and they do not readily cross the blood-brain barrier.

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin of ivermectin. Based on the plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

RESIDUE INFORMATION

Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

WARNING

WARNING! NOT FOR USE IN HUMANS.

The product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report advers effects, obtain an MSDS or for assistance contact Bimeda, Inc. at 1-888-524-6332.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

PRECAUTIONS

Store away from excessive heat (104 degress F/40 degrees C) and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when Bimectin (ivermectin) Pour-On is stored at temperatures below 32 degrees F.

Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Bimectin (ivermectin) Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs: Bimectin (ivermectin) Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, descruction of *Hypoderma larvae* (cattle grubs) at the period when these grubs are in vital areas my cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with Bimectin (ivermectin) Pour-On at the end of the fly season may be re-treated with ivermectin during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

ENVIRONMENTAL SAFETY

Studies indicate that when ivermectin comes in contact with soil, it readily and tightly binds too the soil and becomes inactive over time. Free ivermectin may adversely affect fish or certain aquatic organisms. Do not permit cattle to enter lakes, streams, or ponds for at least 6 hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung or treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependant insects.

PACKAGE INFORMATION

Bimectin (ivermectin) Pour-On is available in a 33.8 fl oz/1 liter bottle with a measure-pour system, an 84.5 fl. oz/2.5 Liter, a 169 fl. oz/5 Liter, a 338 fl. oz/10 Liter bottle and a 676 fl. oz./20 Liter bottle intended for use with appropriate automatic dosing equipment.

PACKAGE LABEL DISPLAY PANEL

Bimectin

(ivermectin)

Pour-On for Cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies Net Contents: 169 fl oz (5 Liter)

WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME AND OTHER SOURCES OF IGNITION.

WARNING! NOT FOR USE IN HUMANS.

ANADA 200-318, Approved by FDA

Bimeda





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ANADA 200-318, Approved by FDA



Manufactured by: Bimeda, Inc. Le Sueur, MN 56058

1BIM007 8BIM003-509

Back Label

Bimed (ivermed POUR-ON FOR

Consult your veterinarian for assistar and control of parasitism.

INDICATIONS: For the treatment and con roundworms (including inhibited *Ostertag* horn flies, sucking and biting lice, and sarc-

See package insert for the complete indicati

Recommended Dose: 1 mL per 22 lb of body

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Keep this and all drugs out o Warning! Flammable! Keep A Open Flame and Other Si

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Product No.: 1BIM007 8BIM003B-509

> LOT: EXP:

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